

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

MARILYN DARCH,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS  
CORPORATION,

Defendant.

Civil Action No.: 1:08-cv-02338

**ANSWER AND DEFENSES OF  
DEFENDANT NOVARTIS  
PHARMACEUTICALS  
CORPORATION TO PLAINTIFF'S  
COMPLAINT**

**JURY DEMAND**

Defendant Novartis Pharmaceuticals Corporation ("NPC"), by and through its counsel, responds to plaintiff's Complaint and Jury Demand ("the Complaint") as follows:

1. The allegations in Paragraph 1 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint and therefore denies the same. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa®.

2. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint and therefore denies the same.

3. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts are "at all times herein mentioned" and therefore NPC is unable to respond to the allegations in Paragraph 3 of the Complaint. To the extent that a response is required, NPC admits that it is a corporation incorporated under the laws of the state of Delaware with its principal offices located in East Hanover, New Jersey.

4. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts are "at all times herein mentioned" and therefore NPC is unable to respond to the

allegations in Paragraph 4 of the Complaint. To the extent that a response is required, NPC admits that it does business in the States of New York and California. NPC denies any remaining allegations in Paragraph 4 of the Complaint.

5. The allegations in Paragraph 5 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 5 of the Complaint and therefore denies the same.

6. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 6 of the Complaint and therefore is unable to respond to the allegations asserted therein. To the extent that a response is required, NPC admits that it tests, labels, markets, distributes, and sells Zometa<sup>®</sup>. NPC denies the remaining allegations in Paragraph 6 of the Complaint.

7. In response to Paragraph 7 of the Complaint, NPC denies that Zometa<sup>®</sup> is a brand name under which NPC sells “zolodrenic” acid. NPC affirmatively avers that Zometa<sup>®</sup> is a brand name under which NPC sells zoledronic acid. NPC admits that Zometa<sup>®</sup> is a bisphosphonic acid. NPC admits that Zometa<sup>®</sup> is given intravenously to cancer patients. NPC denies the remaining allegations in Paragraph 7 of the Complaint.

8. In response to Paragraph 8 of the Complaint, NPC admits that Zometa<sup>®</sup> is approved by the United States Food and Drug Administration (“FDA”) for the indications listed on the product’s label. NPC denies the allegations in Paragraph 8 of the Complaint to the extent that they mischaracterize or misstate information contained on the label for Zometa<sup>®</sup>. NPC denies any remaining allegations in Paragraph 8 of the Complaint.

9. NPC lacks sufficient knowledge or information to determine the meaning plaintiff ascribes to the phrase “product literature” and what time periods plaintiff asserts in Paragraph 9 of the Complaint. Therefore, NPC is unable to respond to the allegations contained therein. To the extent that a response is required, NPC denies the allegations in Paragraph 9 of the Complaint.

10. In response to Paragraph 10 of the Complaint, NPC admits that Aredia<sup>®</sup> and Zometa<sup>®</sup> are bisphosphonic acids. Further, NPC admits that it received reports in 2002 that some patients treated with Aredia<sup>®</sup> and/or Zometa<sup>®</sup> presented with osteonecrosis of the jaw. NPC denies the remaining allegations in Paragraph 10 of the Complaint.

11. NPC admits that in 2004, Dr. Ruggiero and others published an article entitled “Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 cases,” in the Journal of Oral and Maxillofacial Surgery. NPC admits that the quoted language appears in this article, but avers that the article speaks for itself. NPC denies the allegations in Paragraph 11 of the Complaint to the extent that they mischaracterize or misstate information contained in said article. NPC denies any remaining allegations in Paragraph 11 of the Complaint.

12. The allegations in Paragraph 12 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it sent correspondence to medical professionals in September 2004 and May 2005 addressing the subject of osteonecrosis of the jaw. NPC denies the remaining allegations in Paragraph 12 of the Complaint.

13. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 13 of the Complaint and therefore denies the same.

14. The allegations in Paragraph 14 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to determine whether plaintiff was given and/or injected with Zometa<sup>®</sup> and whether plaintiff has osteonecrosis of the jaw and therefore denies the same. NPC denies any remaining allegations in Paragraph 14 of the Complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

15. NPC lacks sufficient knowledge or information to determine whether plaintiff was given and/or injected with Zometa<sup>®</sup> and whether plaintiff was injured and therefore NPC is unable to respond to the allegations in Paragraph 15 of the Complaint and denies the same. The remaining allegations in Paragraph 15 of the Complaint and its subparts (a) through (g) constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 15 of the Complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>. NPC also specifically denies that plaintiff is entitled to any of the relief sought in Paragraph 15 of the Complaint and its subparts (a) through (g).

16. In response to Paragraph 16 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

17. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 17 of the Complaint and therefore is unable to respond to the allegations asserted therein. To the extent that a response is required, NPC admits that it labels, tests, distributes, markets, and sells Zometa<sup>®</sup>. NPC denies the remaining allegations in Paragraph 17 of the Complaint.

18. The allegations in Paragraph 18 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 18 of the Complaint. NPC specifically denies that Zometa<sup>®</sup> is “defective” and/or “unreasonably dangerous.”

19. The allegations in Paragraph 19 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 19 of the Complaint. NPC specifically denies that Zometa<sup>®</sup> is “defective.”

20. The allegations in Paragraph 20 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 20 of the Complaint. NPC specifically denies that Zometa<sup>®</sup> is “defective.”

21. The allegations in Paragraph 21 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 21 of the Complaint. NPC specifically denies that Zometa<sup>®</sup> is “defective.”

22. NPC lacks sufficient knowledge or information to determine whether plaintiff was injured and therefore denies the same. The remaining allegations in Paragraph 22 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 22 of the Complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

23. In response to Paragraph 23 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

24. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 24 of the Complaint and therefore NPC is unable to respond to the allegations contained therein. To the extent that a response is required, NPC admits that it tests, labels, markets, distributes, and sells Zometa<sup>®</sup>. NPC denies the remaining allegations in Paragraph 24 of the Complaint.

25. The allegations in Paragraph 25 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 25 of the Complaint.

26. The allegations in Paragraph 26 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 26 of the Complaint.

27. NPC lacks sufficient knowledge or information to determine whether plaintiff was injured and therefore denies the same. The remaining allegations in Paragraph 27 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 27 of the Complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

28. In response to Paragraph 28 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

29. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 29 of the Complaint and therefore NPC is unable to respond to the allegations contained therein. To the extent that a response is required, NPC admits that it tests, labels, markets, distributes, and sells Zometa<sup>®</sup>. NPC denies the remaining allegations in Paragraph 29 of the Complaint.

30. The allegations in Paragraph 30 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC admits that applicable law imposes certain duties upon manufacturers and distributors of products, but denies that Paragraph 30 of the Complaint accurately sets forth those duties. NPC denies the remaining allegations in Paragraph 30 of the Complaint.

31. The allegations in Paragraph 31 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 31 of the Complaint.

32. The allegations in Paragraph 32 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 32 of the Complaint.

33. NPC lacks sufficient knowledge or information to determine whether plaintiff was injured and therefore denies the same. The remaining allegations in Paragraph 33 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 33 of the Complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

34. In response to Paragraph 34 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

35. The allegations in Paragraph 35 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 35 of the Complaint.

36. The allegations in Paragraph 36 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient



knowledge or information to form a belief as to the truth of the allegations in Paragraph 36 of the Complaint and therefore denies the same.

37. The allegations in Paragraph 37 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 37 of the Complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa®.

38. NPC lacks sufficient knowledge or information to determine whether plaintiff was injured and therefore denies the same. The remaining allegations in Paragraph 38 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 38 of the Complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa®.

39. In response to Paragraph 39 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

40. The allegations in Paragraph 40 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 40 of the Complaint.

41. The allegations in Paragraph 41 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 41 of the Complaint and therefore denies the same.

42. The allegations in Paragraph 42 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 42 of the Complaint.



43. NPC lacks sufficient knowledge or information to determine whether plaintiff was injured and therefore denies the same. The remaining allegations in Paragraph 43 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 43 of the Complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

44. With respect to the allegations in the unnumbered paragraph following Paragraph 43 of the Complaint and its subparts (a) through (c), captioned "PRAYER FOR RELIEF", and beginning with the word "WHEREFORE," these allegations constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies that plaintiff is entitled to any of the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

45. Every allegation in the Complaint that is not specifically and expressly admitted in this Answer is hereby specifically and expressly denied.

#### **AFFIRMATIVE DEFENSES**

1. The Complaint, in whole or part, fails to state a claim or cause of action against NPC upon which relief can be granted.

2. Venue is inconvenient to the parties in the United States District Court for the Southern District of New York and this matter should be transferred to an appropriate jurisdiction.

3. The doctrines contained in Restatement (Second) of Torts § 402A, Comment K, bar plaintiff's claims against NPC in whole or in part.

4. The doctrine(s) contained in Restatement (Third) of Torts, Product Liability §§ 4 and 6, bar plaintiff's claims against NPC in whole or in part.

5. Applicable statutes of limitations or repose bar plaintiff's claims in whole or in part. *See, e.g.*, California Code of Civil Procedure Section 335.1.

6. Plaintiff's misuse or abnormal use of the product or failure to follow instructions bar the plaintiff's claims in whole or in part.

7. The alleged injuries to plaintiff were proximately caused by the misuse, abuse, alteration, and/or failure to properly utilize, maintain, or care for the product by persons other than NPC.

8. If plaintiff used a product sold by NPC, then plaintiff's claims are barred, in whole or in part, because plaintiff assumed the risks disclosed by the product labeling, by the prescribing physicians, or by other persons or entities.

9. Any alleged negligent or culpable conduct of NPC, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of plaintiff's alleged injuries.

10. If plaintiff used a product sold by NPC, plaintiff used the product for "off-label" purposes, which bars the plaintiff's claims.

11. The "learned intermediary" doctrine bars plaintiff's claims.

12. Plaintiff's claims are barred, in whole or in part, because the product at issue was designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

13. Plaintiff's claims are barred, in whole or in part, because the labels and information accompanying the products at issue were approved by the U.S. Food and Drug Administration or other appropriate regulatory agencies.

14. Plaintiff's claims are barred, in whole or in part, by applicable products liability statutes or other law providing absolute or limited immunity or a disputable presumption of immunity against liability for pharmaceutical products approved by the FDA. *See, e.g.*, N.J.S.A. § 2A:58C-5; N.J.S.A. § 2A:58C-4.

15. Plaintiff's claims are barred, in whole or in part, because the product at issue was not defective or unreasonably dangerous in that it complied with, at all relevant times, all applicable government safety standards.

16. Plaintiff's claims are preempted, in whole or in part, by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, modeling, processing, and supply of Aredia<sup>®</sup> and/or Zometa<sup>®</sup>.

17. Plaintiff's claims are barred, in whole or in part, because plaintiff's injuries, if any, were the result of conduct of plaintiff, independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to plaintiff's pre-existing medical conditions.

18. If plaintiff suffered injury or damages as alleged, which is denied, such injury or damage resulted from acts or omissions of persons or entities for which NPC is neither liable nor responsible or resulted from diseases and/or causes that are not related to or connected with any product sold, distributed, or manufactured by NPC. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of plaintiff's alleged injury or damages.

19. Plaintiff's claims are barred, in whole or in part, because plaintiff's alleged injuries, if caused by Zometa<sup>®</sup>, which is denied, was the result of plaintiff's own idiosyncratic reactions.

20. Plaintiff failed to mitigate, which limits plaintiff's damages, if any, in whole or in part.

21. Zometa<sup>®</sup> was fit and proper for its intended purposes and the social utility of the drug outweighed any possible risk inherent in the use of the product.

22. NPC has no legal relationship or privity with plaintiff and owes no duty to plaintiff by which liability could be attributed to it.

23. The claims of plaintiff should be diminished in whole or in part in the amount paid to plaintiff by any party or non-party with whom plaintiff has settled or may settle.

24. Plaintiff's claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

25. NPC made no warranties of any kind, express or implied, or any representations of any nature whatsoever to plaintiff. If any such warranties were made, whether express or implied, which NPC specifically denies, then plaintiff did not rely on any such representations or warranties and/or failed to give notice of any breach thereof.

26. Notwithstanding the claims and contentions of plaintiff, plaintiff received all or substantially all of the benefit from the product that plaintiff hoped and intended to receive, and, to that extent, any damages and/or restitution that plaintiff might be entitled to recover from NPC must be correspondingly reduced.

27. Plaintiff's causes of action are barred in whole or in part by plaintiff's own contributory/comparative negligence.

28. Plaintiff's recovery, if any, shall be reduced by those payments that plaintiff receives from collateral sources.

29. If plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by an NPC product.

30. Plaintiff's claims are barred to the extent that plaintiff seeks relief under laws of states that do not govern plaintiff's claims.

31. To the extent that New Jersey law applies, plaintiff's claims are subsumed and/or barred by the New Jersey Products Liability Act, in whole or in part. *See In re Lead Paint Litigation*, 191 N.J. 405, 436-37, 924 A.2d 484, 503-04 (2007); *Brown ex rel. Brown v. Philip Morris, Inc.*, 228 F. Supp. 2d 506, 515-18 (D.N.J. 2002).

32. To the extent that California law applies, plaintiff's strict liability and warranty claims are barred in whole or in part. *See, e.g., Brown v. Superior Court*, 44 Cal. 3d 1049, 1072 (1988).

33. NPC hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves its right to amend this Answer to assert such defenses.

WHEREFORE, Defendant NPC demands judgment in its favor and against plaintiff, dismissing plaintiff's Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

**JURY DEMAND**

Defendant Novartis Pharmaceuticals Corporation demands a jury trial as to all issues so triable.

Dated: March 31, 2008

Respectfully submitted,

s/ Ethan D. Stein

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**CERTIFICATE OF SERVICE**

I hereby certify that on March 31, 2008, the Answer and Defenses of Defendant Novartis Pharmaceuticals Corporation to Plaintiff's Complaint was filed with the Clerk of the Court and served in accordance with the Southern District's Rules on Electronic Service upon the following parties and participants:

Daniel A. Osborn, Esq.  
Russel H. Beatie, Esq.  
Philip J. Miller, Esq.  
Beatie and Osborn LLP  
521 Fifth Avenue, 34<sup>th</sup> Floor  
New York, NY 10175

I further certify that on March 31, 2008, I served a true and correct copy of the Answer and Defenses of Defendant Novartis Pharmaceuticals Corporation to Plaintiff's Complaint, by United States Mail, postage prepaid, on:

The Powell Law Firm, L.C.  
269 South Beverly Drive  
Suite 1156  
Beverly Hills, CA 90212

The Offices of Jeffrey C. Bogert  
501 Colorado Boulevard  
Suite 208  
Santa Monica, CA 90401

s/ Ethan D. Stein  
Ethan D. Stein